Section b.) Amendments to the Claims.

The text of all claims under examination is shown below in the listing. Claims being amended in this paper include markings indicating changes that have been made relative to the prior version. These changes are shown by strikethrough for deleted matter and underlining for added matter. No accompanying clean version is supplied. The text of pending claims not being currently amended that are under examination are shown in clean version in the listing. Cancelled claims are indicated merely by their status without the text.

Listing of Claims:

Claim 1 (currently amended): In a method for adhering a prosthesis to a human or animal body with an adhesive device, the improvement comprising the use of an adhesive device comprising:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.

Claim 2 (previously presented): The method according to Claim 1 in which the carrier sheet is non-woven and continuous and is made from a material selected from the group consisting of polysaccharide based materials, polyethylene, polyamide, polyurethane, nylon, polyester, polypropylene, polytetrafluoroethylene, and silicone.

Claim 3 (previously presented): The method according to Claim 1 in which the carrier sheet has a density of about 5 to 150 g/m^2 and a thickness in the range of about 0.01 to about 1 mm.

Claim 4 (canceled):

Claim 5 (previously presented): The method according to Claim 1 in which the first and second continuous layers of silicone gel have a thickness in the range of about 0.2 to 5 mm.

Claim 6 (previously presented): The method according to Claim 1 in which the first and second continuous layers of silicone gel are covered by release liners.

Claim 7 (canceled).

Claim 8 (currently amended): A prosthesis having an adhesive device for adhering it to a human or animal body comprising:

a prosthesis having a surface to be adhered to a human or animal body; and

on the surface of the prosthesis to be adhered to the human or animal body, an adhesive device comprising:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body,

wherein the first continuous layer of silicone gel of the adhesive device is adhered to the surface of the prosthesis to be adhered to a human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.

Claim 9 (canceled):

Claim 10 (currently amended): A method for adhering a prosthesis to a human or an animal body comprising:

positioning an adhesive device between the prosthesis and the human or animal body; and

compressing the adhesive device between the prosthesis and the human or animal body, wherein the adhesive device comprises:

a carrier sheet, said carrier sheet having at least two surfaces;

on one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2; said gel having sufficient tack to adhere to the prosthesis; and

on a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2, said gel having sufficient tack to adhere to the human or animal body; and wherein the first and second continuous layers of silicone gel are formed by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups in the presence of a platinum or rhodium catalyst.

Section c.) Remarks.

This reply is in response to the Office Action dated March 4, 2004.

Claims 1-3, 5, 6, 8, and 10 are pending in the application. The claims have been rejected as being unpatentable over Fabo (WO 960907) in view of Luckman (Canadian 2,101,509) under Section 103(a).

The invention relates to a method for adhering a prosthesis to a human or animal body with an adhesive device, and a prosthesis with the adhesive device adhered thereto. The improvement resides in the use of an adhesive device which is a carrier sheet having at least two surfaces. On one surface of the carrier sheet is a first, continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2. The first layer of the gel has sufficient tack to adhere to a prosthesis. On a second surface of the carrier sheet is a second continuous layer of a silicone gel having a density in the range of about 100 to 4500 g/m^2. The second layer of the gel has sufficient tack to adhere to a human body or to an animal body.

In contrast, Fabo fails to teach the claimed method or prothesis. Thus, nothing in Fabo teaches, suggests, anticipates, or renders obvious, a method of using a silicone gel composition to adhere a prosthesis to a human or animal body. Rather, Fabo teaches that the his compositions are used in the healthcare industry as a dressing.

As noted by the Examiner, the Board of Appeals did reject the original claims over Fabo. However the rationale behind the Board's decision was that the top sheet 4 and the protective layer 5 in the Fabo reference were substrates adhered together with the gel. The pending claims however have been limited to a prosthesis and a human or animal body. Nothing in Fabo describes any method relating to adhering a prosthesis to a human or animal body with the gel adhesive.

While Luckman teaches a breast enhancement device adhered to the chest wall of the wearer with an adhesive, the adhesive is Dow Corning Corporation's SILASTIC® Medical Adhesive Silicone, Type A. The Examiner has taken the position that the breast prosthesis in Luckman is adhered to a human body, in the manner claimed in the present invention. In Luckman, there is no carrier sheet having two surfaces that contain a silicone gel. Instead, the device is directly adhered to the chest wall with SILASTIC® Medical Adhesive Silicone, Type A adhesive layer 14.

The Examiner will find attached hereto a Data Sheet and a Material Safety Data Sheet (MSDS) describing SILASTIC® Medical Adhesive Silicone, Type A. As is apparent from a review of the Data Sheet and the MSDS, the adhesive taught in Luckman is not a gel. Rather, it is a structural adhesive or sealant akin to a cement and glue. The composition is sticky and honey like before cure, and then forms a strong rubber with a tack free surface after cure. The cure is initiated and completed when the adhesive is brought into contact with the substrate. It is chemically bonded to the adhered surface, and is intended to provide a permanent attachment that cannot be removed without damaging the substrate.

In particular, the Examiner should note that on the first page of the Data Sheet, the SILASTIC® Medical Adhesive Silicone, Type A is described as a being a translucent paste used to permanently bond materials. On Page 2, it is said to form a tack-free outer skin a few minutes after application. On Page 7 of the MSDS, it is shown to be formed by a reaction involving a catalyst free mixture consisting of an hydroxy-terminated dimethylsiloxane, methylated silica, methyltriacetoxysilane, and ethyltriacetoxysilane. Claims 1, 8, and 10, on the other hand require that the first and second continuous layers of silicone gel according to the invention are formed

by the reaction of a silicone having Si-H groups with a silicone having Si-aliphatically unsaturated groups, and in the presence of a platinum or rhodium catalyst.

The adhesive gels in the present invention have qualities and behavior profiles akin to a pressure sensitive adhesive. In this regard, the gel adhesive-substrate interface does not resist separation when the adhesive is peeled off. Instead, because the gel has excellent wetting, spreadability, and visco-elasticity properties, it is able to quickly adhere to a surface and develop physical interactions with the surface, and not chemical interactions as in a structural adhesive. Thus, the gel can be removed without deteriorating the surface and/or leaving a residue.

Because of these differences, the gel can be characterized as being a *comfortable adhesive*, providing a soft, movable gel mass against the skin, rather than a permanent rubber cement. Moreover, because of these properties, the gel retains its tack after being removed, so it can be easily removed, moved, and reused. In addition, its unique properties allow for quick, easy, and comfortable, repositioning of medical prosthesis.

The Data Sheet on the first page indicates that during the use of the SILASTIC® Medical Adhesive Silicone, Type A, the composition releases acetic acid. It is apparent that this type of adhesive would not be suitable for uses contemplated by the present invention or uses described in Fabo. Thus, it is not considered that one skilled in the art would not seek to use an adhesive composition in a manner inconsistent with its intended use, and which could potentially be detrimental to the surface to which it is to contact, i.e., a human or animal body. In addition, and as noted above, the SILASTIC® Medical Adhesive Silicone, Type A is intended to be used to permanently bond materials, rather than provide an attachment which can be easily removed without causing damage to the underlying surface, as in the present application and as in Fabo.

Thus, it is not seen wherein it would be obvious to one skilled in the art to combine any teaching from Luckman into Fabo, or vice versa for that matter.

Since nothing in Fabo or Luckman teach or disclose the use of gel like adhesives in a method for adhering prosthesis, it is considered that the claims distinguish over the cited references for the reasons stated, and the Examiner is requested to withdraw the rejection and pass the case to issue.

Respectfully submitted,

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Attachment - 11 Pages - Data Sheet & MSDS